



HW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): CHENG, Yung-chi et al.
SERIAL NO.: 10/781,305
FILED: February 18, 2004
FOR: Anti-viral nucleoside analogs and methods for treating viral
Infections, especially HIV infections
GROUP ART UNIT: 1614
EXAMINER: MCINTOSH III, TRAVISS C

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 223313-1450

SUPPLEMENTARY INFORMATION DISCLOSURE STATEMENT

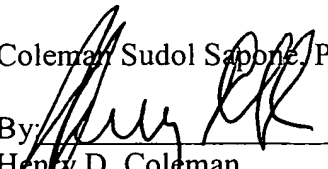
SIR:

Pursuant to the Duty to Disclose under 37 C.F.R. §1.56(a), applicant encloses herewith a copy of Form PTO-1449 listing documents relevant to the background of the invention described and claimed in the above-identified application. For the convenience of the Examiner, copies of the listed documents are enclosed.

Applicant respectfully requests that the Examiner consider the enclosed references in determining the patentability of the claimed invention. Applicant also requests that the Examiner return a copy of enclosed Form PTO-1449 with initials or other marks indicating that the reference has been so considered. If any fee is due, please charge/credit deposit account no. 04-0838.

Respectfully submitted,

Coleman Sudol Sapone, P.C.

By: 
Henry D. Coleman
Reg. No. 32,559
714 Colorado Avenue
Bridgeport, Connecticut 06605-1601
(203)366-3560

Dated: May 24, 2006



CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: "Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on May 24, 2006.

Harold Hull

Harold Hull



INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Att'y Ref: Y03-100US	Serial No: 10/781,305
	Applicant: CHENG, Yung-chi et al.	
	Filing Date: Feb. 18, 2004	Art Unit: 1614

United States Patent Documents						
Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date

Foreign Patent Documents							
Examiner Initial	Publication Number	Publication Date	Country	Class	Subclass	Translation	
						Yes	No

Examiner Initial	Other Documents (by Title, Author Date, Pertinent Pages, Etc.)
	August, E. M., M. E. Marongiu, T. S. Lin, and W. H. Prisoiff. 1988. Initial studies on the cellular pharmacology of 3'-deoxythymidin-2'-ene (d4T): a potent and selective inhibitor of human immunodeficiency virus. <i>Biochem Pharmacol</i> 37:4419-22.
	Bridges, E. G., G. E. Dutschman, E. A. Gullen, and Y. C. Cheng. 1996. Favorable interaction of beta-L(-) nucleoside analogues with clinically approved anti-HIV nucleoside analogues for the treatment of human immunodeficiency virus. <i>Biochem Pharmacol</i> 51:731-6.

Examiner:	Date Considered:
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered; Include a copy of this form with next communication to the applicant.	

	Brinkman, K., H. J. ter Hofstede, D. M. Burger, J. A. Smeitink, and P. P. Koopmans. 1998. Adverse effects of reverse transcriptase inhibitors: mitochondrial toxicity as common pathway. <i>Aids</i> 12:1735-44
	Browne, M. J., K. H. Mayer, S. B. Chafee, M. N. Dudley, M. R. Posner, S. M. Steinberg, K. K. Graham, S. M. Geletko, S. H. Zinner, S. L. Denman, and et al. 1993. 2',3'-dideoxythymidine (d4T) in patients with AIDS or AIDS-related complex: a phase I trial. <i>J Infect Dis</i> 167:21-9
	Chen, C. H., and Y. C. Cheng. 1989. Delayed cytotoxicity and selective loss of mitochondrial DNA in cells treated with the anti-human immunodeficiency virus compound 2',3'-dideoxycytidine. <i>J Biol Chem</i> 264:11934-7
	Chen, C. H., M. Vazquez-Padua, and Y. C. Cheng. 1991. Effect of anti-human immunodeficiency virus nucleoside analogs on mitochondrial DNA and its implication for delayed toxicity. <i>Mol Pharmacol</i> 39:625-8
	Cheng, Y. C. 1978. Thymidine Kinase from Blast Cells of Myelocytic Leukemia, p. 365-371, <i>Methods in Enzymology</i> , vol. LI Academic Press, New York
	Coates, J. A., N. Cammack, H. J. Jenkinson, A. J. Jowett, M. I. Jowett, B. A. Pearson, C. R. Penn, P. L. Rouse, K. C. Viner, and J. M. Cameron. 1992. (-)-2'-deoxy-3'-thiacytidine is a potent, highly selective inhibitor of human immunodeficiency virus type 1 and type 2 replication in vitro. <i>Antimicrob Agents Chemother</i> 36:733-9
	Coates, J. A., N. Cammack, H. J. Jenkinson, I. M. Mutton, B. A. Pearson, R. Storer, J. M. Cameron, and C. R. Penn. 1992. The separated enantiomers of 2'-deoxy-3'-thiacytidine (BCH 189) both inhibit human immunodeficiency virus replication in vitro. <i>Antimicrob Agents Chemother</i> 36:202-5
	De Clercq, E. 1994. HIV resistance to reverse transcriptase inhibitors. <i>Biochem Pharmacol</i> 47:155-69
	Doong, S. L., C. H. Tsai, R. F. Schinazi, D. C. Liotta, and Y. C. Cheng. 1991. Inhibition of the replication of hepatitis B virus in vitro by 2',3'-dideoxy-3'-thiacytidine and related analogues. <i>Proc Natl Acad Sci U S A</i> 88:8495-9
	Dutschman, G. E., E. G. Bridges, S. II. Liu, E. Gullen, X. Guo, M. Kukhanova, and Y. C. Cheng. 1998. Metabolism of 2',3'-dideoxy-2',3'-dideoxy-beta-L(-)-5-fluorocytidine and its activity in combination with clinically approved anti-human immunodeficiency virus beta-D(+) nucleoside analogs in vitro. <i>Antimicrob Agents Chemother</i> 42:1799-804
	Feng, J. Y., A. A. Johnson, K. A. Johnson, and K. S. Anderson. 2001. Insights into the molecular mechanism of mitochondrial toxicity by AIDS drugs. <i>J Biol Chem</i> 276:23832-7
	Gelmon, K., J. S. Montaner, M. Fanning, J. R. Smith, J. Falutz, C. Tsoukas, J. Gill, G. Wells, M. O'Shaughnessy, M. Wainberg, and et al. 1989. Nature, time course and dose dependence of zidovudine-related side effects: results from the Multicenter Canadian Azidothymidine Trial. <i>Aids</i> 3:555-61

Examiner:

Date Considered:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered; Include a copy of this form with next communication to the applicant.

	Gosselin, G., R. F. Schinazi, J. P. Sommadossi, C. Mathe, M. C. Bergogne, A. M. Aubertin, A. Kim, and J. L. Imbach. 1994. Anti-human immunodeficiency virus activities of the beta-L enantiomer of 2',3'-dideoxycytidine and its 5-fluoro derivative in vitro. <i>Antimicrob Agents Chemother</i> 38:1292-7
	Hamamoto, Y., H. Nakashima, T. Matsui, A. Matsuda, T. Ueda, and N. Yamamoto. 1987. Inhibitory effect of 2',3'-didehydro-2',3'-dideoxynucleosides on infectivity, cytopathic effects, and replication of human immunodeficiency virus. <i>Antimicrob Agents Chemother</i> 31:907-10
	Haraguchi, K., S. Takeda, H. Tanaka, T. Nitanda, M. Baba, G. E. Dutschman, and Y. C. Cheng. 2003. Synthesis of a Highly Active New Anti-HIV Agent 2', 3'-Didehydro-3'-deoxy-4'-ethynylthymidine. <i>Bioorg Med Chem Letter</i> 13:3775-3777
	Johnson, A. A., A. S. Ray, J. Hanes, Z. Suo, J. M. Colacino, K. S. Anderson, and K. A. Johnson. 2001. Toxicity of antiviral nucleoside analogs and the human mitochondrial DNA polymerase. <i>JBiol Chem</i> 276:40847-57
	Larder, B. A. 1995. Viral resistance and the selection of antiretroviral combinations. <i>J Acquir Immune Defic Syndr Hum Retrovirol</i> 10 Suppl 1:S28-33
	Larder, B. A., B. Chesebro. and D. D. Richman. 1990. Susceptibilities of zidovudinesusceptible and -resistant human immunodeficiency virus isolates to antiviral agents determined by using a quantitative plaque reduction assay. <i>Antimicrob Agents Chemother</i> 34:436-41
	Lee, L. S., and Y. C. Cheng. 1976. Human deoxythymidine kinase. I.Purification and general properties of the cytoplasmic and mitochondrial isozymes derived from blast cells of acute myelocvtic leukemia. <i>J Biol Chem</i> 251:2600-2604
	Lewis, W., and M. C. Dalakas. 1995. Mitochondrial toxicity of antiviral drugs. <i>Nat Med</i> 1:417-22
	Lin, T. S., M. Z. Luo, M. C. Liu, S. B. Pai, G. E. Dutschman, and Y. C. Cheng. 1994. Antiviral activity of 2',3'-dideoxy-beta-L-5-fluorocytidine (beta-L-FddC) and 2',3'-dideoxy-beta-L-cytidine (beta-L-ddC) against hepatitis B virus and human immunodeficiency virus type 1 in vitro. <i>Biochem Pharmacol</i> 47:171-4
	Lin, T. S., M. Z. Luo, M. C. Liu, S. B. Pai, G. E. Dutschman, and Y. C. Cheng. 1994. Synthesis and biological evaluation of 2',3'-dideoxy-L-pyrimidine nucleosides as potential antiviral agents against human immunodeficiency virus (HIV) and hepatitis B virus (HBV). <i>J Med Chem</i> 37:798-803
	Lin, T. S., M. Z. Luo, M. C. Liu, Y. L. Zhu, E. Gullen, G. E. Dutschman, and Y. C. Cheng. 1996. Design and synthesis of 2',3'-dideoxy-2',3'-didehydro-beta-L-cytidine (beta-L-d4C) and 2',3'-dideoxy 2',3'-didehydro-beta-L-5-fluorocytidine (beta-LF4C), two exceptionally potent inhibitors of human hepatitis B virus (HBV) and potent inhibitors of human immunodeficiency virus (HIV) in vitro. <i>J Med Chem</i> 39:1757-9
	Lin, T. S., R. F. Schinazi, M. S. Chen, E. Kinney-Thomas, and W. H. Prusoff. 1987. Antiviral activity of 2',3'-dideoxycytidin-2'-ene (2',3'-dideoxy-2',3'-didehydrocytidine) against human

Examiner:	Date Considered:
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered; Include a copy of this form with next communication to the applicant.	

	immunodeficiency virus in vitro. <i>Biochem Pharmacol</i> 36:311-6
	Lin, T. S., R. F. Schinazi, and W. H. Prusoff. 1987. Potent and selective in vitro activity of 3'-deoxythymidin-2'-ene (3'-deoxy-2',3'-didehydrothymidine) against human immunodeficiency virus. <i>Biochem Pharmacol</i> 36:2713-8
	Lu, Z. H., R. Zhang, and R. B. Diasio. 1993. Comparison of dihydropyrimidine dehydrogenase from human, rat, pig and cow liver. Biochemical and immunological properties. <i>Biochem Pharmacol</i> 46:945-52
	Maag, H., R. M. Rydzewski, M. J. McRoberts, D. Crawford-Ruth, J. P. Verheyden, and E. J. Prisbe. 1992. Synthesis and anti-HIV activity of 4'-azido- and 4'-methoxynucleosides. <i>J Med Chem</i> 35:1440-51
	Medina, D. J., C. H. Tsai, G. D. Hsiung, and Y. C. Cheng. 1994. Comparison of Mitochondrial Morphology, Mitochondrial DNA Content, and Cell Viability in Cultured Cells Treated with Three Anti-Human Immunodeficiency Virus Dideoxynucleosides. <i>Antimicrob Agents Chemother</i> 38:1824-1828
	Mellors, J. W., G.E. Dutschman, G.J. Im L. Tramontano, S. R. Winkler, and Y. C. Cheng. 1992. In vitro selection and molecular characterization of human immunodeficiency virus-1 resistant to non-nucleoside inhibitors of reverse transcriptase. <i>Mol Pharmacol</i> 41:446-51
	O-Yang, C., H. Y. Wu, B. Fraser-Smith, and K. A. M. Walker. 1992. Synthesis of 4'-Cyanothymidine and Analogs as Potent Inhibitors of HIV. <i>Tetrahedron Letters</i> 33:37-40
	Parker, W. B., and Y.C.Cheng.1995."Disruption of Energy Metabolism and Mitochondrial Function", p. 483-490, <i>Neurotoxicology: Approaches and Methods</i> . Academic Press Inc., New York
	Parker, W. B., and Y. C. Cheng. 1994. Mitochondrial Toxicity of Antiviral Nucleoside Analogs. <i>The Journal of NIH Research</i> 6:57-61
	Richman, D. D. 1993. Resistance of clinical isolates of human immunodeficiency virus to antiretroviral agents. <i>Antimicrob Agents Chemother</i> 37:1207-13
	Richman, D. D., M. A. Fischl, M. H. Grieco, M. S. Gottlieb, P. A. Volberding, O. L. Laskin, J. M. Leedom, J. E. Groopman, D. Mildvan, M. S. Hirsch, and et al. 1987. The toxicity of azidothymidine (AZT) in the treatment of patients with AIDS and AIDS-related complex. A double-blind, placebo-controlled trial. <i>N Engl JMed</i> 317:192-7
	Schinazi, R. F., C. K. Chu, A. Peck, A. McMillan, R. Mathis, D. Cannon, L. S. Jeong, J. W. Beach, W. 13. Choi, S. Yeola, and et al. 1992. Activities of the four optical isomers of 2',3'-dideoxy-3'-thiacytidine (BCH-189) against human immunodeficiency virus type 1 in human lymphocytes. <i>Antimicrob Agents Chemother</i> 36:672-6
	Sommadossi, J. P., Z. Zhou, M. J. Hitchcock, H. M. McClure, M. el Kouni, and E. Cretton. 1992. Catabolism of 2',3'-Didehydro-2',3'-DideoxyThymidine (D4T) in Isolated Hepatocytes and in Rhesus Monkeys. <i>Proc. Annu. Meeting American Cancer Research</i> 33:A3253. Univ. of Alabama

Examiner:

Date Considered:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered; Include a copy of this form with next communication to the applicant.

	Yarchoan, R., J. M. Pluda, R. V. Thomas, H. Mitsuya, P. Brouwers, K. M. Wyvill, N. Hartman, D. G. Johns, and S. Broder. 1990. Long-term toxicity/activity profile of 2',3'-dideoxyinosine in AIDS or AIDS-related complex. <i>Lancet</i> 336:526-9
--	--

Examiner:

Date Considered:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered; Include a copy of this form with next communication to the applicant.